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The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 20

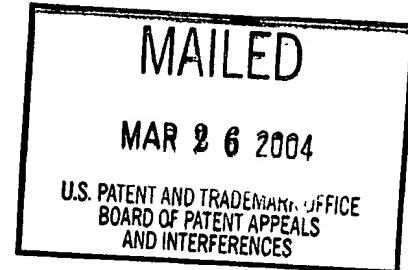
## UNITED STATES PATENT AND TRADEMARK OFFICE

### BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ALAN R. HIRSCH

Appeal No. 2003-1468  
Application No. 09/707,655

ON BRIEF



Before WINTERS, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

#### DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 24-33, 35, 36, 38, 41, 42, and 44-46, all of the claims remaining. Claim 24 is representative and reads as follows:

24. An article of manufacture, comprising, packaged together:

a unit dosage amount of an odorant packaged in a container, to alter blood flow to the vagina when inhaled by a female individual; wherein the odorant is selected from the group consisting [of] a mixture of a licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants; and

instructions for administering the odorant to alter blood flow to the vagina.

The examiner relies on the following reference:

Doty, "The Smell Identification Test™ Administration Manual," Sensonics, Inc., pp. 1-22 (1983)

Claims 24-33, 35, 36, 38, 41, 42, and 44-46 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled.

Claims 24, 26-33, 35, 36, 38, 41, 42, and 44-46 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite.

We reverse both rejections.

#### Background

Appellant's specialty appears to be using smells to induce physiological or psychological changes in people. The record contains copies of Appellant's patents for using odorants to treat claustrophobia or agoraphobia (Patent 5,759,521, titled "Method of altering perception of relative space of an area"), to treat male impotence or erectile dysfunction (Patent 5,885,614, titled "Use of odorants to treat male impotence, and an article of manufacture therefor"), and to treat headaches (Patent 6,106,837, titled "Method of treating headaches, and article of manufacture therefor").

The instant application discloses a method of using odorants to treat female sexual dysfunction. Existing "[t]reatments for enhancing or inhibiting female sexual capacity and response" include counseling, medications, and psychotherapy. Specification, page 3. "However, such treatments have not been totally effective, are invasive[,] can cause unwanted side effects, and are

inconvenient and complex." Id. The disclosed method, by contrast, is "non-invasive[,] . . . convenient, safe, and easy to perform." Id.

The method defined by the claims on appeal focuses on the aspect of the disclosed method concerned with enhancing, rather than inhibiting, sexual response. In the specification's words,

the odorant can be administered in an amount sufficient to increase vaginal blood flow of the female individual. By increasing vaginal blood flow, the female individual will experience increased or enhanced sexual arousal. Examples of odorants and odorant mixture[s] that can be administered to increase vaginal blood flow by about 10-30%, include . . . a mixture of licorice-based odorant and banana nut bread odorant, a mixture of licorice-based odorant and cucumber odorant, . . . a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants.

Page 4.

The specification also discloses that "[s]uch odorants are commercially available, for example, from International Flavors and Fragrances, Inc. (IFF, New York, NY), Energy Essentials, AromaTech, Inc. (Somerville, NJ), Florasynth, Inc (Teterboro, NJ), and as essential oils." Id.

#### Discussion

Representative claim 24 is directed to a kit comprising a mixture of odorants (licorice-based and banana nut bread, licorice-based and cucumber, lavender and pumpkin pie, or baby powder and chocolate), and instructions for administering the odorant (e.g., "scratch and sniff"; see specification, page 7). The claim also recites a "unit dosage amount" limitation; the amount can be, e.g., 25-55 decismel units. Specification, page 5.

The examiner rejected most of the claims as indefinite and rejected all of the claims as nonenabled.

1. Definiteness

We will start with definiteness. See In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971) (Analysis of a claim under § 112 "should begin with the determination of whether the claims satisfy the requirements of the second paragraph. . . . [T]he claims must be analyzed first in order to determine exactly what subject matter they encompass.").

The examiner rejected the claims as indefinite, on the basis that the smells recited in the claims are not adequately defined. The examiner asserted, for example, that the smell of pumpkin pie or banana nut bread can differ depending on the ingredients in a particular recipe; that baby powders from different manufacturers can have different smells; that the smell of cucumbers can vary depending on, among other things, their ripeness; and that different licorice-based odorants and chocolates can have different smells. See the Examiner's Answer, page 5. He concluded that "[t]he subjective nature of the mixtures of recited odorants . . . causes these claims to be very ambiguous and unclear." Id.

Appellant argues that those of ordinary skill in the odorant arts "would be able to ascertain whether a substance had a chocolate aroma, a licorice aroma, a banana nut bread aroma, a cucumber aroma, a lavender aroma, or a baby powder aroma, regardless of whether the substance was the commercial source disclosed, or another synthetic or natural source." Appeal Brief, page 6.

"The standard of indefiniteness is somewhat high; a claim is not indefinite merely because its scope is not ascertainable from the face of the claims."

Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1342, 65 USPQ2d 1385, 1406 (Fed. Cir. 2003). Rather, a "claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention." Id.

In this case, we agree with Appellant that those skilled in the art would understand the scope of the claims. The record supports Appellant's position that calling particular smells, e.g., "chocolate" or "licorice" is standard practice in the odorant arts. See, e.g., the present specification at page 12, which lists various commercially available odorants that have the specific smells recited in the claims. See also Doty, which is an administration manual for a "smell identification test". Among the smells that test subjects were asked to identify were "chocolate", "licorice", and "pumpkin pie". See page 5. Thus, Doty provides evidence that the smells recited in the claims are recognizable; i.e., that "chocolate", for example, defines a particular type of smell.

The examiner's reasoning does not contradict this evidence. The examiner argues that, for example, "chocolate" is indefinite because "milk chocolate has a distinct odor from dark chocolate." Examiner's Answer, page 5. This reasoning does not show that the claims are indefinite. Even though milk chocolate may smell different from dark chocolate, both smells would seem to be recognizable as types of "chocolate" smells; the examiner has not shown that

those skilled in the art would not recognize both milk chocolate and dark chocolate as having a "chocolate" odor.

Likewise, the examiner may be correct that the smell of cucumbers will vary "based on brand, species, age/ripeness, geographic location in which it is grown, etc." Examiner's Answer, page 5. However, the examiner has presented no basis for concluding that these variables would render the smell of a cucumber unrecognizable; even though cucumbers may vary, all of them would be expected to smell recognizably like cucumbers.

The same goes for the rest of the smells recited in the claims: the examiner has not shown that the terms used in the claims are so ill-defined that those skilled in the art would be unable to tell whether a given smell is or is not within the scope of the claim limitations. Therefore, the examiner has not shown that the scope of the claims could not reasonably be ascertained by those skilled in the art.

Claims are in compliance with 35 U.S.C. § 112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits." Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1987). That standard is met here. The rejection for indefiniteness is reversed.

## 2. Enablement

The examiner also rejected the claims as being non-enabled. The examiner's reasoning with regard to enablement is similar to his reasoning with

regard to indefiniteness. Specifically, the examiner argues that “[t]he instantly claimed odorants are highly subjective with respect to the actual odors being encompassed and, thus, are not enabled.” Examiner’s Answer, page 4. That is, because the particulars of the smells recited in the claims can vary, and because it is unpredictable what effect changing the smell would have on the treated subject, “it would take undue experimentation without a reasonable expectation of success for one of skill in the art to prepare and use an article of manufacture having the unusual disclosed/claimed functional effect.” Id.

Appellant argues that practicing the claims would not require undue experimentation because “[t]he characteristics of the odorants in the mixtures recited in the claims are well understood in the odorant arts, and one skilled in the odorant arts would readily ascertain and provide suitable odorant mixtures from various sources that have the recited odorant character (e.g., mixture of licorice-based and cucumber odorants, etc.) and that would achieve the desired effect.” Appeal Brief, page 9.

We agree with Appellant. The examiner bears the initial burden of showing nonenablement. In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). (“When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification.”). Carrying that burden requires evidence or sound scientific reasoning showing that practicing the full scope of the claims

would have required undue experimentation. See In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991) ("[E]nabling requires that the specification teach those in the art to make and use the invention without 'undue experimentation.' . . . That some experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'")  
(Emphasis in original.)

In this case, the examiner's case of nonenablement rests on his assertion that the smells of different cucumbers, chocolates, etc. vary, and that this variability is likely to change the effect of the smells on the female subjects being treated. The examiner, however, has provided no evidence to show that any variability in the smells of different samples of cucumber, chocolate, etc. would change the effect of such smells from the effect described in the specification.

For example, the specification asserts that a combination of lavender and pumpkin pie odorants is suitable for practicing the presently claimed invention. That assertion is entitled to a presumption of enablement throughout its scope. See In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) ("[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.") (Emphasis in original.) Therefore, the examiner bears the burden of showing that practicing

the claimed invention using different lavender and pumpkin pie odorants would have required undue experimentation.

The examiner has not carried this burden. We can accept the examiner's position that there is some variation in the range of smells that would be characterized as "lavender" or "pumpkin pie". The examiner has provided no evidence or sound scientific reasoning, however, to support his position that such variability is a source of unpredictability in the effect of different smells that are recognizable as "lavender" or "pumpkin pie". In support of the assertion of unpredictability, the examiner cites only Doty, which he characterizes as disclosing that "there are numerous variables such as an individual's occupation, general health, psychological state, and age which play a role in assessing sensory function of smell." Examiner's Answer, page 4.

This evidence is inadequate to support the examiner's case. The examiner has provided no reasoning and cited no evidence to show that women's occupation, health, age, or psychological state is likely to affect their physiological reactions to different lavender or pumpkin pie smells. The examiner's position therefore lacks adequate evidentiary or scientific basis. The rejection for nonenablement is reversed.

#### Other Issues

The combination of lavender and pumpkin pie smells seems to have similar effects in both men and women. This combination of odorants is claimed in the instant application as part of an article for enhancing female sexual activity

and is also claimed in Appellant's '614 patent as part of an article for treating male impotence. Instant claims 24 and 41 read as follows (emphasis added):

24. An article of manufacture, comprising, packaged together:  
a unit dosage amount of an odorant packaged in a container,  
to alter blood flow to the vagina when inhaled by a female  
individual; wherein the odorant is selected from the group  
consisting [of] a mixture of a licorice-based and banana nut bread  
odorants, a mixture of licorice-based and cucumber odorants, a  
mixture of a lavender and pumpkin pie odorants, and a mixture of  
baby powder and chocolate odorants; and  
instructions for administering the odorant to alter blood flow  
to the vagina.

41. An article of manufacture, comprising, packaged together:  
a unit dosage amount of an odorant packaged in a container,  
to increase blood flow to the vagina when inhaled by a female  
individual; wherein the odorant is selected from the group  
consisting of a mixture of a licorice-based and cucumber odorants,  
a mixture of a lavender and pumpkin pie odorants, and a mixture of  
a baby powder and chocolate odorants; and  
instructions for administering the odorant to increase blood  
flow to the vagina.

Claims 2 and 5 of the '614 patent read as follows (emphasis added):

2. A method of increasing penile blood flow in a male individual,  
comprising:  
administering to the male by inhalation of an odorant in an  
amount effective to increase penile blood flow;  
the odorant selected from the group consisting of a mixture  
of lavender and pumpkin pie, a mixture of doughnut and black  
licorice, and a mixture of pumpkin pie and doughnut.

5. An article of manufacture, comprising:  
(a) an odorant recited in claim 2 packaged within a  
container, wherein the odorant when inhaled by a male individual is  
effective to increase penile blood flow in the male; and  
(b) instructions for use of the odorant according to the  
method of claim 2.

Thus, it would appear that the only difference between the "lavender and  
pumpkin pie" embodiment of the instant claims and the same embodiment of the

'614 patent's claim 5 is in the content of the instructions packaged together with the odorants.

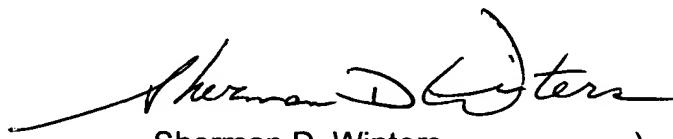
The content of printed instructions is not sufficient, by itself, to patentably distinguish two articles that are otherwise the same. See, e.g., In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983): "Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability. Although the printed matter must be considered, in that situation it may not be entitled to patentable weight." (Footnote omitted.)

Upon return of this application, the examiner should consider whether, in the absence of a terminal disclaimer, any of the instant claims should be rejected for obviousness-type double patenting in view of Appellant's '614 patent.

Summary

We reverse the rejections for indefiniteness and nonenablement, but recommend that the examiner consider whether all of the present claims are patentably distinct from Appellant's issued claims.

REVERSED



Sherman D. Winters  
Administrative Patent Judge



Donald E. Adams  
Administrative Patent Judge

) BOARD OF PATENT

) APPEALS AND

) INTERFERENCES



Eric Grimes  
Administrative Patent Judge

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